

state commerce of "Testo-Glan Male Formula" (regular strength and double strength) and "Fem-Tone Female Formula," or any similar article of drug which would bear a label or would be accompanied by labeling containing false and misleading representations of the nature alleged in the complaint.

4757. Testo-Glan Male Formula. (Inj. No. 275.)

PETITION FILED: On 9-15-54, in the E. Dist. N. Y., the U. S. attorney filed a petition for an order to show cause why Leo Shine, t/a Glanex Products and Medical Products, Floral Park, N. Y., should not be punished for criminal contempt of the permanent injunction which had been entered against him on 4-19-54 (preceding notice of judgment No. 4756).

CHARGE: The petition alleged that, following the entry of the injunction, and between 4-28-54 and 5-27-54, the defendant caused interstate shipments of *Testo-Glan Male Formula* (regular strength and double strength) to be made from Floral Park, N. Y., to Dayton and Niles, Ohio; Norfolk, Va.; Los Angeles, Calif.; Chicago, Ill.; Atlanta, Ga.; and Hartford, Conn.; that, when so shipped, the article was misbranded under 502 (a) in that its labeling contained false and misleading representations that the article contained physiologically active glandular substances; that the glandular constituents of the article were of value in overcoming glandular deficiencies in the human male; that the article would increase male power; that it was an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness, and irritability; that it contained hormonal activity equivalent to therapeutically significant amounts of testosterone; and, that by reason of such shipments, the defendant was in criminal contempt of the permanent injunction.

DISPOSITION: On 9-16-54, the order to show cause was issued, and on 10-11-54, the defendant pleaded guilty to violation of the injunction. On 11-14-54, the court fined the defendant \$500.

4758. Alfa-Tone and Cab-Ext (2 seizure actions). (F. D. C. No. 37357. S. Nos. 64-766/7 L.)

QUANTITY: 1,524 unlabeled 90-tablet btls. and 250 labeled 90-tablet btls. of *Alfa-Tone* and 650 unlabeled 50-tablet btls. and 500 labeled 50-tablet btls. of *Cab-Ext* at Milton-Freewater, Oreg., in the possession of Dr. A. V. Downs, D. C.

SHIPPED: 7-7-54 and 7-14-54, from Lamar, Colo.

LABEL IN PART: (Btl.) "Alfa-Tone Each tablet contains 4 grs. water soluble Alfalfa Extract. 2 grs. of Alfalfa Seed Extract. 0.1 gr. of Chlorophyll" and "Cab-Ext Each tablet contains 400 Mg. of cabbage extract. As an aid in relieving ulcers and inflammation of stomach."

ACCOMPANYING LABELING: Loose labels designated "Alfa-Tone" and "Cab-Ext" and leaflets designated "Alfa-Tone As An Aid For Hay Fever, Low Vitality, Arthritis, Neuritis, Anemia, and Low Blood Pressure" and "Cabbage Juice."

RESULTS OF INVESTIGATION: Both articles were shipped from Lamar, Colo., in unlabeled bottles, and, upon their receipt by the consignee, the above-described labels were applied to a number of bottles. The leaflets were printed locally for the consignee and were distributed with the articles to various health store accounts serving the retail trade.

LIBELED: On or about 1-25-55, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the articles while held for sale contained false and misleading representations that the *Alfa-Tone* was an adequate and

effective treatment for hay fever, low vitality, arthritis, neuritis, anemia, low blood pressure, and diabetes, and that the *Cab-Ext* was an adequate and effective treatment for ulcers and inflammation of the stomach.

DISPOSITION: 2-18-55. No claimant having appeared, the court entered decrees of condemnation and ordered that the articles be destroyed. Thereafter, a motion was made by Dr. A. V. Downs to set aside such decrees, and on 9-20-55, the court handed down the following decision on the motion:

SOLOMON, District Judge: "The motion to set aside the decree in condemnation in each of the above cases is denied.

COMMENT

"The respondent seeks to set aside and vacate the Decree of Condemnation entered in both of the cases on the 18th day of February, 1955. In Civil 7819, the court ordered 984 bottles of tablets labeled 'Alfa-Tone,' together with 500 product labels and 100 descriptive leaflets destroyed. In Civil 7820, the court ordered 480 bottles of tablets labeled in part 'Cab-Ext,' together with 200 descriptive leaflets destroyed.

"There is no contention that the procedural requirements governing these cases have not been strictly met. The respondent was given ample time within which to answer the libel or otherwise appear, and he failed to do so.

"However, respondent contends that the tablets themselves are not harmful or deleterious and that if the leaflets which accompanied the tablets are destroyed, the legitimate purposes of the Federal Food, Drug, and Cosmetic Act will have been accomplished.

"I have examined the report of the analyses of the tablets made by the Charlton Laboratories for the respondent and by the Division of Nutrition of the Department of Health, Welfare, and Education for the libelant. Neither report shows that the tablets are themselves either harmful or deleterious. However, I am convinced that these tablets will serve no worthwhile purpose in the treatment of disease or in the remedying of nutritional deficiencies.

"The accompanying literature indicates that wild and unsupported claims were made concerning the effectiveness of these tablets in the treatment of disease. Even though the literature is destroyed, the return of these tablets to the defendant would, in all probability, result in similar claims being made orally. In my opinion, these tablets are salable only if accompanied by false and misleading statements, and their return to the defendant will only lead to exploitation of the people to whom they are sold."

4759. Hyrocain. (F. D. C. No. 37097. S. No. 64-762 L.)

QUANTITY: 49 display cartons, 12 cartoned tubes each, at Seattle, Wash.

SHIPPED: 6-8-54, from New York, N. Y., by the American Pharmaceutical Co.

LABEL IN PART: (Tube) "APC One Ounce Hyrocain Antibiotic, Antihistaminic And Anesthetic Cream Containing per Gram: Pyrillamine Maleate 10 mg., Benzocaine 10 mg., Tyrothricin 0.5 mg., in a special soothing, non-irritant, non-staining washable base."

ACCOMPANYING LABELING: Leaflet designated "Completely New! Antibiotic, Anesthetic, Antihistaminic Cream Helps Heal," a 2-page letter designated "Hyrocain A New Antibiotic and Anaesthetic Cream," and window banners designated "Hyrocain Stops Itch."

LIBELED: 9-21-54, W. Dist. Wash.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, eczema, skin infections, folliculitis, seborheic dermatitis, nummular eczema, neurodermatitis, and herpes genitalis; and the above-mentioned 2-page letter contained the statement "In order for this product to be released to the public it had to go through clinical testing in a leading allergy clinic and evidence presented to the Food and Drug Administration to